THE UNIVERSITY OF MICHIGAN

REGENTS COMMUNICATION

Approved by the Regents

ACTION REQUEST

March 17, 2006

Subject:

Option Agreement between the University of Michigan and

TRS, LLC

Action Requested: Approval of Option Agreement

Preamble:

A statutory conflict of interest situation was identified by the Office of Technology Transfer while reviewing the technology transfer agreement which then triggered a review by the OVPR Conflict of Interest Review Committee. A plan for management of the possible risks associated with the conflict of interest was then developed by the Committee and agreed to by the parties involved.

This proposed Option Agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Drs. Scott Hollister, Frank LaMarca, Stephen Feinberg, and Chia-Ying Lin are all employees of the University of Michigan ("University") and are partial owners of TRS, LLC ("TRS"). The law permits such an Agreement provided it is disclosed to the executive officers and approved in advance by a 2/3 vote of the Regents of the University of Michigan.

Background:

Dr. Scott Hollister, an Associate Professor in Biomedical Engineering, Dr. Frank La Marca, a Clinical Assistant Professor in Neurosurgery, Dr. Stephen Feinberg, a Professor in Oral and Maxillofacial Surgery, and Dr. Chia-Ying Lin, a Research Investigator in Neurosurgery, are all partial owners of a for-profit company called TRS. TRS was formed recently to commercialize regenerative tissue engineering, and desires an option to license the following technologies from the University:

- UM File No. 2129, entitled: "Design Methodology for Tissue Engineering Scaffolds and Biomaterial Implants" (Juan Taboas, Tien-Min Chu, Scott Hollister)
- UM File No. 2142, entitled: "Functionally Tailored Composite Devices for Tissue Regeneration and Bioactive Factor Delivery" (James Santosa, Suman Das, Paul Krebsbach, Hollister)
- UM File No. 1704, entitled: "Rapid Vascularization of Bioengineered Tissues" (William Murphy, David Mooney, David Kohn, Martin Peters)
- UM File No. 1704d1, entitled: "Mineralization and Biological Modification of Biomaterial Surfaces" (Murphy, Mooney, Kohn, Peters)
- UM File No. 3361, entitled: "Engineered Scaffolds for Intervertebral Disc Repair and Regeneration" (Hollister, La Marca, Sara Mantilla, Das, Chia-YingLin)

- UM File No. 3360, entitled: "Designed Degradable Cage Coated with Mineral Layers for Spine Interbody Fusion" (Chia-Ying Lin, Murphy, Hollister, Das)
- UM File No. 2753, entitled: "A New Approach for Designing Biodegradable/ Bioresorbable Tissue Augmentation/Reconstruction Devices" (Hollister, Chia-Ying Lin)
- UM File No. 2954, entitled: "A Biodegradable Implant for Intertransverse Process Fusion" (Hollister, Karen Bovid, Lin, Frank La Marca)
- UM File No. 2915, entitled: "Image-based design software" (Hollister)
- UM File No. 2955, entitled: "Integrated Elastic and Permeability" (Lin, Hollister)
- UM File No. 2130, entitled: "Controlled micro/macro porous 3D plastic polymer and ceramic/cement composite scaffold fabrication and applications thereof" (Chu, Krebsbach, Rachel Maddox, Hollister)
- UM File No. 2504, entitled: "An Integrated Global Layout and Local Microstructure Topology Optimization Approach for Spinal Cage Design and Fabrication (Lin, Cheng-Yu Lin, Hollister)
- UM File No. 1853, entitled: "CAD-MRI and CT-based production of Tissues for Tissue Engineering" (Mooney, Jonathon Rowley, Lawrence Bonassar)
- UM File No. 1360, entitled: "Gas Foaming to Create Open Pore Structure" (Mooney, Leatrese Harris, Lonnie, Shea)
- UM File No. 1360p1, entitled: "Sustained Drug Delivery from Structural Matrices" (Elly Liao, Mooney, Shea, William Peters)

Parties to the Agreement:

The Regents of the University of Michigan and TRS

Option Terms:

Option terms include giving TRS a one year option to an exclusive license with the right to grant sublicenses. TRS will pay for ongoing patent expenses, perform technical diligence, and provide a business plan that describes TRS' intention and ability to develop and commercialize the licensed technology, which will include: 1) an identified, committed, experienced and capable management team; 2) an appropriate commercialization strategy; and 3) a capitalization plan indicating sufficient access to capital to enable the commercialization plan to be executed. Terms of the subsequent license agreement would include a royalty on sales and reimburse of patent costs. The University will retain ownership of the licensed technology and may continue to further develop it and use it internally. No use of University services or facilities, nor any assignment of University employees, is obligated or contemplated under the agreement. Standard disclaimers of warrantees and indemnification apply, and the contract may be amended by consent of the parties.

Pecuniary Interest:

The pecuniary interests of Drs. Hollister, La Marca, Feinberg, and Lin arise from their ownership interest in TRS. They have waived any personal participation in the sharing of revenue received by the University.

Net Effect:

The Office of Technology Transfer has negotiated and finalized the terms of a world-wide exclusive option agreement for patents related to UM OTT File Nos. 2129, 2142, 1704, 1704d1, 3361, 3360, 2753, 2954, 2915, 2955, 2130, 2504, 1853, 1360, and 1360p1 for the field of use of human and animal health.

TRS will obtain use and commercialization rights to the above listed University technology.

Recommendations:

This matter has been reviewed and approved by the OVPR Conflict of Interest Review Committee. In light of this disclosure and our finding that the Agreement was negotiated in conformance with standard University practices, I recommend that the Board of Regents approve the Option Agreement between the University and TRS.

Respectfully Submitted,

Stephen R. Forrest

Vice President for Research

March 2006